A Single-center Study Evaluating Alma TED™ and a Peptide-based Topical Hair Care Formula for Female and Male Pattern Hair Loss

Shraddha Desai, MD, FAAD
Duly Health and Care, Naperville, USA

Background

Female or male pattern hair loss (FPHL/MPHL), is a common hair disorder characterized by progressive hair thinning and loss, particularly in the frontal, crown and vertex regions of the scalp.[1] FPHL affects approximately 30 million women and MPHL affects 50 million men in the US, with a 40-50% risk of development in people over 50 years of age.[2] While medically benign, hair loss can negatively affect self-esteem, emotional state, and social activity, which may impair health-related quality of life.[3]

The progressive hair loss characteristic of FPHL/MPHL is thought to be primarily mediated by the miniaturization of hair follicles, resulting in the conversion of large (terminal) hairs into small (vellus) hairs and the shortening of successive anagen (growth phase) cycles.[1,5] The reduced anagen phase leads to increasingly thinner, shorter hairs ultimately unable to penetrate the epidermis.[4,6]

Treatment options for FPHL/MPHL include medical, surgical, and light-based interventions.[1] Current FDA-approved therapies include topical minoxidil and oral finasteride (only for MPHL); however, these options come with undesirable side effects including excessive facial hair growth, dermatological conditions, and sexual dysfunction.[1] Platelet-rich plasma (PRP) is an emerging treatment with few side effects, but the harvesting and processing of PRP is time-consuming, treatment effect is variable, and many consider injections painful.[1,7] Low-level light therapy (LLLT) offers another alternative to standard treatments but has a low level of evidence for efficacy.[1,8] Thus, an unmet clinical need remains for consistent treatment options with few side effects that prevent hair loss and restore growth.

Here, we present a treatment for FPHL/MPHL using the Alma TED™ system + Hair Care Formula (Alma Lasers, Inc, Chicago, IL)- a combination of proprietary technology with a novel peptide-based topical hair formulation. Alma TED™ is a Class I medical device using a propriety tip (Patent No: US 10,238,849 B2) engineered with Impact Delivery™. Coupling the device with the TED™ + Hair Care Formula (cosmetics) addresses hair loss concerns by facilitating hair and scalp health and fortifying follicular integrity. Here, the efficacy and safety of this needle-free alternative are assessed.

Materials and Methods

To assess the benefits and effectiveness of the device and hair care formulation in FPHL/MPHL, a single-center, open-label study of 11 participants (eight women and three men) was conducted.

Patients enrolled in the study were treated at Duly Health and Care Dermatology in Naperville, IL. Eligible patients were 18 years or older with a history of FPHL/MPHL according to the Ludwig and Norwood scales.[9] Key exclusion criteria included current use of PRP, history of hair transplantation, immune system disorders, trigeminal neuralgia, and skin disease. Patients with an active infection in the treatment area or known malignancy were also excluded.

Participants were treated for a total of three sessions, 30 days apart. Treatment effect was assessed at 30 and 90 days following the last treatment. For each treatment session **(Table 1)**, all treatment zones were first primed with the Alma TED™ system to condition the stratum corneum for two minutes each (30% Impact). The peptide-based hair formulation was then applied throughout a single treatment zone. Next, the Alma TED™ system was used again for two minutes or until the hair is dry (50% Impact). These three steps were repeated for each treatment zone. Female treatment zones included the frontal scalp, crown, and temples, while male treatment zones included the crown, vertex, and frontotemporal scalp.

Table 1. Technical Details of a Single Treatment Session*

Procedure Step	Description	Product	Impact Settings	Time
Step 1	Prime	Alma TED™	30%	2 min
Step 2	Application of hair formulation	Peptide-based Hair Care Formula	NA	
Step 3	Treat	Alma TED™	50%	2 min**

*Steps 1-3 are repeated in order in each treatment area.
**Or until hair is dry.

At each treatment session, participants answered questions (Y/N) on whether they had observed reduced hair shedding and/or increased hair growth and if they experienced any pain using the 11-point Subject Pain Assessment Scale (0=no pain-10=extreme pain). Changes in global presentation and hair density were measured using the GroTrack hair growth tracking system (GRO Technologies, Santa Monica, CA) at baseline, each treatment visit, and 30 and 90 days following the final treatment. Terminal and vellus counts per cm^2 were recorded. Hair growth was also evaluated using the 5-point Subject- and Physician-reported Global Aesthetic Improvement scale and 5-point Subject

Satisfaction **(Table 2)**.

Table 2. Patient Self-Assessment Scores

Scale	Assessment Scores (# of Patients)	
	30-Day Follow-Up	90-Day Follow-Up
Subject Global Aesthetic Improvement Scale (S-GAIS)	Avg score=3.8	Avg score=3.9
1=Worse	0	0
2=No Change	0	1
3=Improved	4	1
4=Much improved	3	5
5=Very much improved	2	2
Subject Satisfaction	Avg score=3.7	Avg score=3.9
1=Very dissatisfied	0	0
2=Dissatisfied	0	1
3=Satisfied	6	1
4=Much Satisfied	0	5
5=Very Much Satisfied	3	2

Results

Data from nine participants (six women and three men) were evaluated. Demographics are shown in (**Table 3)**.

All (100%) participants reported a decrease in shedding (80% after the first treatment and 20% after the second treatment). Increased hair growth was also noted by all (100%) participants, with 40% reporting improvement following the first treatment, and the remaining following treatment two (40%) and three (10%).

Table 3. Demographic Data

Parameter	Value
Cases Evaluated	9
Females	6
Males	3
Median age (range)	55 (29-78)
Ethnicity	
Caucasian	5
Indian Asian	2
African or African American	2
Previous PRP treatment*	4

*PRP consisted of 2-4 treatments with minimal to mild response.

At the 30-day follow-up visit, 100% of patients were improved, much improved, or very much improved (S-GAIS average 3.8), and 100% of participants were satisfied, much satisfied, or very much satisfied. At 90 days, S-GAIS and satisfaction scores both increased to 3.9 **(Table 4)**. In agreement with S-GAIS, the mean P-GAIS score of the nine participants was 3.9 at the 90-day follow-up. Assessment of the Ludwig (female) and Norwood (male) Scales demonstrated a 1.2 and 1.7-grade improvement, respectively.

Hair density measurements per cm^2 as determined by GroTrack analysis demonstrated improvements in hair density at 30 and 90 days (24% and 34% increase, respectively) across all treatment areas and both genders **(Table 5)**. Growth was most pronounced in the temples for both genders, but hair density increased more dramatically in women (52% at day 30 and 65% at day 90; **Table 5**).

Table 4. Average Improvement in Hair Density per cm^2 by Treatment Region

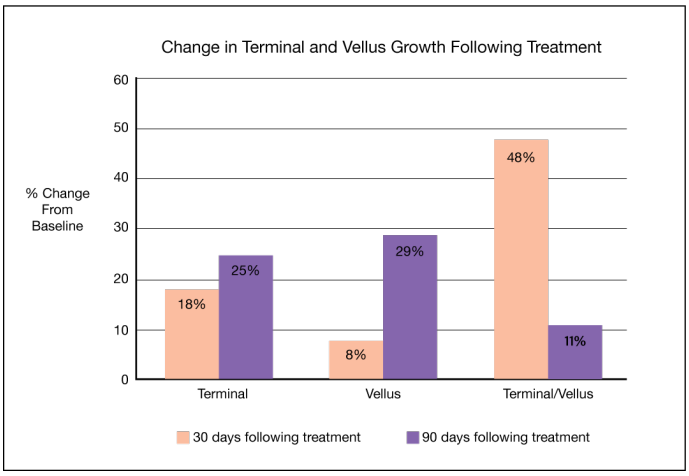
Patient	N	Frontal	Crown	Vertex	Right Temple	Left Temple	Bilateral Temples	Overall Average
30-Day Follow-up Hair Density Summary								
Female	6	8%	18%	-2%	42%	62%	52%	25%
Male	3	52%	15%	6%	15%	26%	20%	21%
Both Genders	9	21%	17%	1%	32%	50%	41%	24%
90-Day Follow-up Hair Density Summary								
Female	6	19%	29%	10%	35%	81%	58%	36%
Male	3	50%	21%	21%	26%	33%	30%	30%
Both Genders	9	31%	26%	14%	32%	65%	49%	34%

Terminal and vellus hair counts per cm^2 were reported by GroTrack and confirmed by manual count **(Table 5)**. Relative to baseline, terminal hair count increased for both genders across all treatment areas at 30 days following treatment and continued to increase at 90 days **(Table 5)**. The average increase of terminal hair in all areas combined represents an 18% increase relative to baseline at 30 days and a 25% increase at 90 days post-treatment **(Figure 1)**. When averaged across all treatment zones, an increase in terminal hair count was observed at 30 days and continued at 90 days **(Table 5)**. The change in vellus hair is reflected by an 8% increase in vellus count at 30 days following treatment, which increased to 29% at 90 days **(Figure 1)**. Unlike terminal hair count, an increase in vellus hair count was not observed at 30 days or 90 days post-treatment in the crown. The terminal-to-vellus ratio (T/V) for all treatment zones combined increased at 30 days following treatment, representing a 48% increase relative to baseline. The degree of the change was reduced to an 11% increase at 90 days following treatment **(Figure 1)**.

Table 5. Terminal and Vellus Count per cm^2

Days Following Treatment	Frontal	Crown	Vertex	Right Temple	Left Temple	Overall Average
Terminal						
Baseline	61.33	63.11	69.67	48.33	47.22	57.93
30 Days	72.29	73.11	70.22	62.13	64.56	68.46
90 Days	72.38	78.78	76.78	62.25	72.00	72.44
Vellus						
Baseline	4.78	6.56	5.33	4.78	4.11	5.11
30 Days	4.57	6.33	4.89	4.63	7.11	5.51
90 Days	6.71	6.11	6.22	7.00	7.00	6.61
Terminal/Vellus (T/V)						
Baseline	12.84	9.63	13.06	10.12	11.49	11.43
30 Days	23.11	13.23	22.82	15.85	9.73	16.95
90 Days	12.24	14.06	16.10	9.37	11.46	12.65

Figure 1. Change in Terminal and Vellus Growth for All Treatment Areas Combined

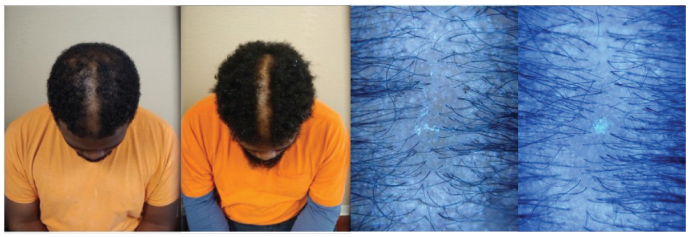


Importantly, none of the participants reported pain (mean score=0) at any of the sessions and there were no adverse events recorded throughout the evaluation period. Two case examples are presented in Figures 2 and 3. Case 1 **(Figure 2)** shows the transformation in hair density for a female patient and Case 2 **(Figure 3)** shows a male patient.

Figure 2. Case 1: Diffuse Female Pattern Hair Loss. At 90 days, overall hair density improved 27% with frontal hair density improving 21%.

Baseline | 90 days Post Tx 3 | Baseline Hair Density: 55/cm^2 | 90 days Post Tx 3 Hair Density:68/cm^2 (+24%)

Figure 3. Case 2: Diffuse Male Pattern Hair Loss. At 90 days, overall hair density improved 22% with crown hair density improving 24%.



Baseline | 90 Days Post Tx 3 | Baseline Hair Density: 55/cm^2 | 90 Days Post Tx 3 Hair Density: 68/cm^2 (+24%)

Discussions

The Alma TED™ system + Hair Care Formula is safe and efficacious at increasing terminal hair growth and hair density in all evaluated treatment zones for FPHL/MPHL. This treatment demonstrated improvement via all evaluated metrics, including objective measures of hair density, terminal/vellus hair counts, and change on the Ludwig/Norwood scales as well as subjective measures of global improvement (P-GAIS and S-GAIS), hair growth/shedding surveys, and subject satisfaction. Positive results were apparent early on and durable through 90 days.

A durable improvement in hair density across all treatment areas and both genders was noted, and analysis of hair composition revealed that terminal hair density increased over the course of the study, consistent with FPHL/MPHL reversal. Somewhat surprisingly, the T/V ratio decreased from 30 to 90 days following treatment. However, the decrease in the ratio is a result of an increase in vellus hair rather than a reduction in terminal hair. For example, a decrease in the telogen (resting phase) to anagen (growth phase) ratio of the vellus hair from 30 to 90 days may be indicative of improvement considering its increase is a histopathological feature of FPHL/MPHL.[10]

As an efficacious treatment with no observed side effects, this therapy represents a favorable treatment option that helps meet the need for safe and effective alternatives to standard hair loss treatments.[11] Side effects of minoxidil and finasteride may be a deterrent for some patients. For example, women may avoid minoxidil for fear of excessive facial hair growth.[1] Minoxidil also loses effectiveness over time, and the hair gained during treatment falls out upon discontinuation.[12] Additionally, the potentially irreversible male sexual dysfunction occurring with finasteride may prevent its widespread usage among men, and its efficacy has not been established in women.[1,13] In contrast, the Alma TED™ system + Hair Care Formula appears to be an effective treatment option for hair restoration with no observed adverse effects.

When compared with PRP and LLLT, the Alma TED™ system + Hair Care Formula is distinguished by its convenience and patient comfort. The absence of pain in this treatment may be a differentiating advantage over PRP. Furthermore, the harvesting and processing of PRP is time-consuming and disruptive to clinical workflow, whereas LLLT is inconvenient to the patient as it may require daily sessions for an extended period to achieve results.[1,7,14] In contrast, the Alma TED™ system + Hair Care Formula is an easy and convenient procedure capable of achieving durable results over three short sessions.

Conclusion

In this single-center evaluation, treatment of FPHL/MPHL using the Alma TED™ system + Hair Care Formula was improved hair density and global appearance. Importantly, participants recognized decreases in shedding and increases in growth early following treatment initiation and are overall highly satisfied with the results. Results are apparent as early as one month after treatment initiation and durable for at least three months. To support the promising data presented here, longer-term follow-up with larger sample sizes at multiple sites is warranted.

References

1. Nestor MS, Ablon G, Gade A, Han H, Fischer DL. Treatment options for androgenetic alopecia: Efficacy, side effects, compliance, financial considerations, and ethics. J Cosmet Dermatol. 2021;20(12):3759-3781.

2. Peyravian N, Deo S, Daunert S, Jimenez JJ. The Inflammatory Aspect of Male and Female Pattern Hair Loss. J Inflamm Res. 2020;13:879-881.
3. Huang CH, Fu Y, Chi CC. Health-Related Quality of Life, Depression, and Self-esteem in Patients With Androgenetic Alopecia: A Systematic Review and Meta-analysis. JAMA Dermatol. 2021;157(8):963-970.
4. Ho CH, Sood T, Zito PM. Androgenetic Alopecia. In: StatPearls. StatPearls Publishing; 2022. Accessed March 5, 2023. http://www.ncbi.nlm.nih.gov/books/NBK430924/
5. Paus R, Cotsarelis G. The biology of hair follicles. N Engl J Med. 1999;341(7):491-497. doi:10.1056/NEJM199908123410706
6. Lolli F, Pallotti F, Rossi A, et al. Androgenetic alopecia: a review. Endocrine. 2017;57(1):9-17.
7. Stevens J, Khetarpal S. Platelet-rich plasma for androgenetic alopecia: A review of the literature and proposed treatment protocol. Int J Womens Dermatol. 2018;5(1):46-51.
8. Pillai JK, Mysore V. Role of Low-Level Light Therapy (LLLT) in Androgenetic Alopecia. J Cutan Aesthet Surg. 2021;14(4):385-391.
9. Gupta M, Mysore V. Classifications of Patterned Hair Loss: A Review. J Cutan Aesthet Surg. 2016;9(1):3-12.
10. Vujovic A, Del Marmol V. The Female Pattern Hair Loss: Review of Etiopathogenesis and Diagnosis. Biomed Res Int. 2014;2014:767628.
11. Hausauer AK, Jones DH. Evaluating the Efficacy of Different Platelet-Rich Plasma Regimens for Management of Androgenetic Alopecia: A Single-Center, Blinded, Randomized Clinical Trial. Dermatol Surg. 2018;44(9):1191-1200.
12. Olsen EA, Weiner MS, Amara IA, DeLong ER. Five-year follow-up of men with androgenetic alopecia treated with topical minoxidil. J Am Acad Dermatol. 1990;22(4):643-646.
13. Schweiger ES, Boychenko O, Bernstein RM. Update on the pathogenesis, genetics and medical treatment of patterned hair loss. J Drugs Dermatol. 2010;9(11):1412-1419.
14. Borowiecka JM, Dalewski B, Pałka Ł. Effectiveness of Platelet-Rich Plasma in the Treatment of Androgenic Alopecia Compared to Placebo and Topical Minoxidil: A Systematic Review. Scientia Pharmaceutica. 2023;91(1):4.
15. Pakhomova EE, Smirnova IO. Comparative Evaluation of the Clinical Efficacy of PRP-Therapy, Minoxidil, and Their Combination with Immunohistochemical Study of the Dynamics of Cell Proliferation in the Treatment of Men with Androgenetic Alopecia. International Journal of Molecular Sciences. 2020;21(18):6516.
16. Jimenez JJ, Wikramanayake TC, Bergfeld W, et al. Efficacy and safety of a low-level laser device in the treatment of male and female pattern hair loss: a multicenter, randomized, sham device-controlled, double-blind study. Am J Clin Dermatol. 2014;15(2):115-127.
17. Esmat SM, Hegazy RA, Gawdat HI, et al. Low level light-minoxidil 5% combination versus either therapeutic modality alone in management of female patterned hair loss: A randomized controlled study. Lasers Surg Med. 2017;49(9):835-843.

A Single-center Study Evaluating Alma TED™ and a Peptide-based Topical Hair Care Formula for a Variety of Hair Loss Concerns

Lady Dy, MD, FAAD
Dy Dermatology, Glenview, USA

Background

Hair loss, whether sudden or insidious, arises from a multitude of clinical etiologies and is broadly categorized as either cicatricial (scarring) or non-cicatricial (non-scarring). While medically benign, hair loss of any type often has a negative effect on self-esteem, emotional state, and social functioning, which can significantly impact health-related quality of life.[1]

Scarring hair loss, while less common, is characterized by the active destruction of the hair follicle by inflammatory infiltration.[2] This irreparable damage to the follicle leads to permanent hair loss.[2] Some of the more common types of scarring hair loss are lichen planopilaris and central centrifugal scarring hair loss (CCSA).[3]

Non-scarring hair loss is very common and is primarily characterized by thinning hair.[2] Common types of non-scarring hair loss include telogen effluvium, characterized by stress-related shedding, and certain autoimmune hair loss; but, the most common type of non-scarring hair loss is female and male pattern hair loss (FPHL/MPHL) which affects approximately 30 million women and 50 million men in the US.[4] It presents with progressive hair thinning and loss, particularly in the frontal, crown and vertex regions of the scalp.[5] Initial symptoms can develop as early as the teenage years with 40% of women developing FPHL by age 50, and 50% of men developing MPHL after age 50.[4] The progressive hair loss characteristic of FPHL/MPHL is thought to be primarily mediated by the miniaturization of hair follicles, resulting in the conversion of large (terminal) hairs into small (vellus) hairs and the shortening of successive anagen (growth phase) cycles.[5,6] The reduced anagen phase leads to increasingly thinner, shorter hairs that are ultimately unable to penetrate the epidermis.[7,8]

Treatment options for FPHL/MPHL include medical, surgical, and light-based interventions.[5] Current FDA-approved therapies include topical minoxidil and oral finasteride (only for MPHL); however, these options come with undesirable side effects including excessive facial hair growth, dermatological conditions, and sexual dysfunction.[5] Platelet-rich plasma (PRP) is an emerging treatment with few side effects, but the harvesting and processing of PRP is time-consuming, the treatment effect is variable, and many patients consider injections painful.[5,9] Low-level light therapy (LLLT) offers another alternative to standard treatments but has low evidence for efficacy.[5,10] Immunosuppressant therapies such as intralesional corticosteroid injections for scarring types of hair loss are usually used in combination with other topical therapies (i.e., anti-dandruff shampoo and topical steroids) often without meaningful effect on hair regrowth.[11] Oral janus kinase (JAK) inhibitors, another type of immunomodulatory therapy, are now used for certain autoimmune types of hair loss. While effective, long-term therapy is likely required as hair loss is found to recur in these patients within three months of discontinuing JAK inhibitors.[12] But, the long-term effect of blocking T-cell-mediated inflammatory response is not known.[12] Thus, an unmet clinical need remains for consistent treatment options with few side effects that arrest the progression of hair loss and restore growth.

Here, we present a treatment for various types of hair loss using the Alma TED™ system + Hair Care Formula (Alma Lasers, Inc., Chicago, IL), a combination of proprietary technology with a novel peptide-based topical hair formulation. Alma TED™ is a Class I medical device using a propriety tip (Patent No: US 10,238,849 B2) engineered with Impact Delivery™. Coupling the device with the TED™ + Hair Care Formula (cosmetics) addresses hair loss concerns by facilitating hair and scalp health and fortifying follicular integrity. Here, the efficacy and safety of this needle-free alternative are assessed.

Materials and Methods

To assess the benefits and effectiveness of the device and hair care formulation in various hair loss types, a single-center, open-label evaluation of 50 participants (45 women and five men) was conducted.

Patients enrolled in the study were treated at Dy Dermatology in Glenview, IL. Eligible participants were 18 years or older with a history of hair loss classified as grade II-IV on the Hamilton Norwood Scale or any grade on the Savin Scale.[13] Hair loss types included FPHL/MPHL, telogen effluvium, autoimmune, lichen planopilaris, and central centrifugal scarring hair loss. Participants on concurrent therapies were required to be stable for a minimum of six months prior to the evaluation period. Key exclusion criteria included hair loss classified as Hamilton Norwood grade VI-VII, the use of any new prescriptions or OTC products for hair loss during the study period or in the six months prior to the evaluation period, and any dramatic change in hair styling that would make it difficult to evaluate outcomes.[13] Current use of PRP, history of hair transplantation, immune system disorders, trigeminal neuralgia, and skin disease affecting the scalp were also excluded. Participants with an active infection in the treatment area or known malignancy were also excluded.

Participants were treated for a total of three sessions, 30 days apart.

Treatment effect was assessed at 30 days following the last treatment. For each treatment session **(Table 1)**, a single treatment zone was first primed with the Alma TED™ system to condition the stratum corneum for two minutes (30% Impact). The peptide-based hair formulation was then applied throughout the single treatment zone. Next, the Alma TED™ system was used again for two minutes or until the hair was dry (50% Impact). These three steps were repeated in order for each treatment zone. Female treatment zones included the frontal scalp, crown, and temples, while male treatment zones included the crown, vertex, and frontotemporal scalp.

Table 1. Technical Details of a Single Treatment Session*

Procedure Step	Description	Product	Impact Settings	Time
Step 1	Prime	Alma TED™	30%	2 min
Step 2	Application of hair formulation	Peptide-based Hair Care Formula	NA	
Step 3	Treat	Alma TED™	50%	2 min**

*Steps 1-3 are repeated in order in each treatment area.
**Or until hair is dry.

At each treatment session, participants answered questions (Y/N) on whether they had observed reduced hair shedding and/or increased hair growth, and if they experienced any pain using the 11-point Subject Pain Assessment scale (0=no pain-10=extreme pain). Subjective and objective appearance in hair density was evaluated using a 2-point assessment method (improved/not improved). Participants were further evaluated using the 5-point Subject Satisfaction scale. One participant was monitored using the GroTrack hair growth tracking system (GRO Technologies, Santa Monica, CA) at baseline and 30 days following the final treatment. Total hair density per cm^2 was recorded as part of this assessment. Two participants were monitored for long-term follow-up.

This clinical evaluation was conducted following the principles outlined in the current revised version of the Declaration of Helsinki, Good Clinical Practice (CGP), and in compliance with all applicable laws and regulatory requirements relevant to the use of medical devices in the US.

Results

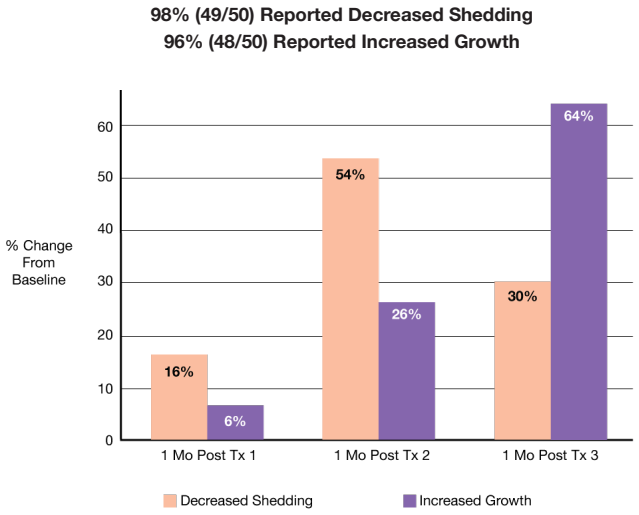
Data from 50 participants (45 women and five men) were evaluated. Except for a single case of non-scarring autoimmune hair loss, all other hair loss types evaluated were responsive to treatment with the Alma TED™ system, resulting in a 98% (49/50) favorable response rate **(Table 2)**.

Table 2. Responsiveness by Hair Loss Type

Primary Hair Loss Type	Subjects	Completed	Responded
Female Pattern Hair Loss	35	35	35
Male Pattern Hair Loss	5	5	5
Central Centrifugal Scarring Alopecia (CCSA)	5	5	5
Telogen Effluvium	3	3	3
Lichen Planopilaris	1	1	1
Alopecia Areata	1	1	0
	50	50	49 (98%)

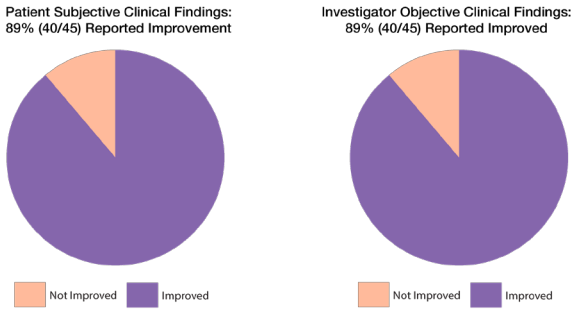
Decreased shedding was reported by 98% (49/50) of participants: 16% after the first treatment, 54% after the second treatment, and 30% after the third treatment **(Table 3)**. Increased hair growth was reported by 96% (48/50) of participants: 6% after the first treatment, 26% after the second treatment, and 64% after the third treatment **(Table 3)**.

Table 3. Changes in Hair Shedding and Growth



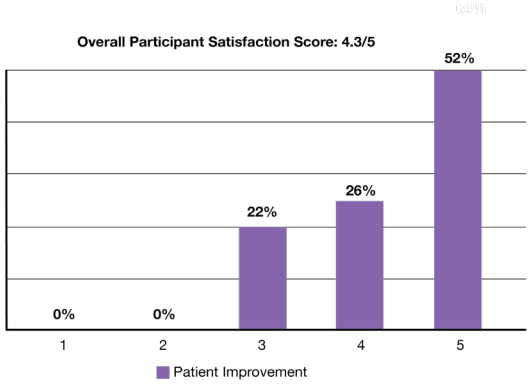
At the 30-day follow-up visit, 89% (40/45) of patients reported visible improvement in hair density appearance **(Table 4)**. The investigator's assessment of objective clinical improvement in hair density appearance was aligned at 89% (40/45) **(Table 4)**. Of the five patients whose hair density did not appear to improve at the 30-day follow-up, one developed non-scarring autoimmune type of hair loss during the evaluation period; and, the other four went on to show objective clinical improvement after the 30-day evaluation period, as these were active patients of the practice who received continued care.

Table 4. Subjective and Objective Clinical Improvement in Hair Density Appearance



All (100%) participants were either satisfied, much satisfied, or very much satisfied at the 30-day follow-up with an average satisfaction score of 4.3/5 **(Table 5)**.

Table 5. Participant Satisfaction Scores

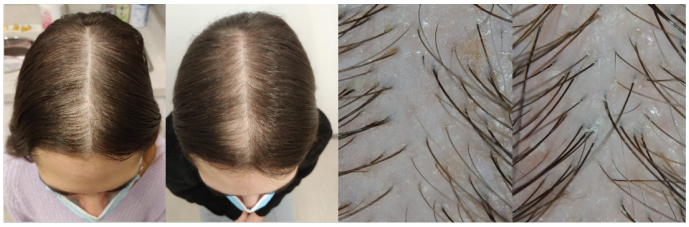


Overall Satisfaction Scale (1=very dissatisfied, 2=dissatisfied, 3=satisfied, 4=much satisfied, 5=very much satisfied)

Importantly, in the 150 treatment sessions administered, there were only four instances of minor discomfort reported (mean pain score=0.057) and there were no adverse events recorded throughout the evaluation period.

Four case examples are presented in Figures 1-4. Case 1 **(Figure 1 and Table 6)** shows the transformation in hair density for a female patient with FPHL. Case 2 **(Figure 2)** shows the transformation in hair regrowth for a female patient with CCSA. And cases 3 and 4 **(Figures 3-4)** show the long-term transformation in hair regrowth with MPHL and FPHL, respectively. Cases 3 and 4 are long-term patients of the practice who went on to receive a fourth treatment following the evaluation period that further enhanced clinical outcomes.

Figure 1. Case 1: Diffuse Female Pattern Hair Loss. At 30 days following three treatments, crown hair density improved by 75%.



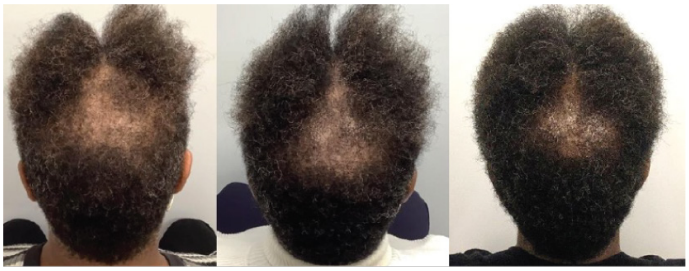
Baseline | 1 Mo Post 3 Tx | Baseline Crown Hair Density: 82/cm² | 1 Mo Post 3 Tx Crown Hair Density: 144/cm² 75% Improvement

Total hair density measurements per cm² as determined by GroTrack analysis (confirmed by manual count) increased on average by 58% demonstrating significant improvements in hair density at 30 days across all locations measured—frontal, crown, and vertex **(Table 6)**.

Table 6. Case 1: Change in Total Hair Density per cm² in FPHL

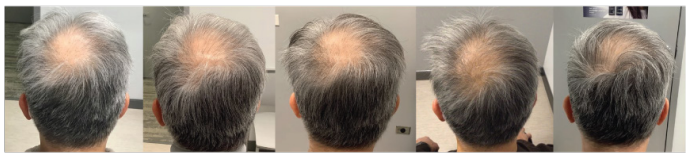
Location	Baseline	30-Day Follow-up	Change
Frontal	82	120	46%
Crown	82	144	75%
Vertex	96	148	54%

Figure 2. Case 2: Central Centrifugal Scarring Hair Loss. Early hair regrowth is visible following treatment initiation, with significant regrowth achieved 30 days following three treatments.



Baseline | 1 Mo Post 1 Tx | 1 Mo Post 3 Tx

Figure 3. Case 3: Diffuse Male Pattern Hair Loss. Early hair regrowth is visible following treatment initiation, with significant regrowth achieved 30 days following four treatments.



Baseline Sept 2021 | 1 Mo Post 1 Tx Pct 2021 | 1 Mo Post 2 Tx Nov 2021 | 1 Mo Post 3 Tx Dec 2021 | 1 Mo Post 4 Tx June 2022

Figure 4. Case 4: Diffuse Female Pattern Hair Loss. Shedding was triggered following a stressful event five months post three treatments with a fourth treatment restoring hair growth.

Baseline Oct 2021	1 Mo Post 3 Tx Jan 2022	5 Mo Post 3 Tx May 2022	4 Mo Post 4 Tx Sept 2022

Discussion

The Alma TED™ system + Hair Care Formula is safe and efficacious at increasing hair growth in many types of hair loss. This treatment demonstrated strong improvement via all evaluated metrics which included subjective and objective clinical assessment of hair density appearance, hair density measurement, as well as hair growth/shedding surveys, and participant satisfaction. Positive results were apparent early after initiating treatment and durable through 30 days. The only type of hair loss that did not respond to treatment was one case of non-scarring autoimmune hair loss; this is an expected outcome as the Alma TED™ system + Hair Care Formula is not intended to address underlying autoimmune conditions resulting in hair loss.

While some participants were naïve to hair loss treatments, the majority were receiving concurrent therapy. To clearly evaluate the potential additional benefit of treatment with the Alma TED™ system + Hair Care Formula, these participants were required to be stable (i.e., no change in therapies used or changes in hair shedding or growth pattern) for a minimum of six months prior to the evaluation period.

As an efficacious treatment with no observed side effects, this therapy represents a favorable treatment option that helps meet the need for safe and effective alternatives to standard hair loss treatments.[14] Side effects of minoxidil and finasteride may be a deterrent for some patients. For example, women may avoid minoxidil for fear of excessive facial hair growth.[5] Minoxidil can also cause transient hair shedding, potentially heightening a patient's anxiety level; and, the hair gained during treatment falls out upon discontinuation.[15] Additionally, the controversial irreversible male sexual dysfunction occurring with finasteride may prevent its widespread usage among men, and its efficacy has not been established in women.[5,16] In contrast, the Alma TED™ system + Hair Care Formula appears to be an effective treatment option for hair restoration with no observed adverse effects.

Similarly to minoxidil, JAK inhibitors also see that hair gained during treatment falls out upon discontinuation.[12] The additional immunomodulatory effects may be a deterrent for others to adopt this therapy for either short or long-term duration. However, the Alma TED™ system + Hair Care Formula may be a unique adjunctive therapy to help maintain hair growth achieved by JAK inhibitors.

When compared with PRP and LLLT, the Alma TED™ system + Hair Care Formula is distinguished by its convenience and patient comfort. The minimal discomfort noted in this evaluation was likely due to the novelty of the technique and associated sound, and one instance of the tip being applied to the scalp while the device was tuning. While tuning, the tip temperature increases which may cause mild discomfort; therefore, skin contact with the tip during device calibration should be avoided. Other clinical evaluations have noted a pain score of zero. This high degree of patient comfort may be an additional differentiating advantage over PRP. Furthermore, the harvesting and processing of PRP is time-consuming and disruptive to clinical workflow, whereas LLLT is inconvenient to the patient as it may require daily sessions for an extended period to achieve visible results.[5,9,17] In contrast, the Alma TED™ system + Hair Care Formula is an easy and convenient procedure capable of achieving meaningful results over three short sessions.

Hair loss is increasingly affecting younger individuals, surprising many who are only aged in their 20s, 30s, or 40s. Environmental influences such as higher reported levels of stress, diet-related nutrient deficiencies, common medications, and certain infections are likely contributing to hair loss in younger adults.[18,19,20] Thus, the Alma TED™ system + Hair Care Formula has wide clinical utility for those aged 18 years and older who are experiencing hair loss.

Maintenance therapy varied among participants depending on their hair loss type and progression. Maintenance therapy was performed once every three months for those using the Alma TED™ system + Hair Care Formula as a monotherapy. Maintenance therapy was performed once every three to six months for those receiving a multimodality treatment approach. Adjustments were made according to the patient's personal medical needs and goals.

Conclusion

In this single-center evaluation, treatment of various hair loss types using the Alma TED™ system + Hair Care Formula improved the appearance of hair density by decreasing shedding and improving hair growth. Importantly, participants recognized these treatment benefits early following treatment initiation and are overall highly satisfied with the results. Results are apparent as early as one month after treatment initiation and durable through 30 days. To support the promising data presented here, longer-term follow-up and further hair metrics analysis are warranted.

References

1. Huang CH, Fu Y, Chi CC. Health-Related Quality of Life, Depression,

and Self-esteem in Patients With Androgenetic Alopecia: A Systematic Review and Meta-analysis. JAMA Dermatol. 2021;157(8):963-970.

2. Levinbook, WS. Alopecia areata - dermatologic disorders. Merck Manuals Professional Edition. September 2022. Accessed May 15, 2023. https://www.merckmanuals.com/professional/dermatologic-disorders/hair-disorders/alopecia-areata.

3. Moure ER, Romiti R, Machado MC, Valente NY. Primary cicatricial alopecias: a review of histopathologic findings in 38 patients from a clinical university hospital in Sao Paulo, Brazil. Clinics (Sao Paulo). 2008;63(6):747-752. doi:10.1590/s1807-59322008000600007

4. Peyravian N, Deo S, Daunert S, Jimenez JJ. The Inflammatory Aspect of Male and Female Pattern Hair Loss. J Inflamm Res. 2020;13:879-881.

5. Nestor MS, Ablon G, Gade A, Han H, Fischer DL. Treatment options for androgenetic alopecia: Efficacy, side effects, compliance, financial considerations, and ethics. J Cosmet Dermatol. 2021;20(12):3759-3781.

6. Paus R, Cotsarelis G. The biology of hair follicles. N Engl J Med. 1999;341(7):491-497. doi:10.1056/NEJM199908123410706

7. Ho CH, Sood T, Zito PM. Androgenetic Alopecia. In: StatPearls. StatPearls Publishing; 2022. Accessed March 5, 2023. http://www.ncbi.nlm.nih.gov/books/NBK430924/

8. Lolli F, Pallotti F, Rossi A, et al. Androgenetic alopecia: a review. Endocrine. 2017;57(1):9-17.

9. Stevens J, Khetarpal S. Platelet-rich plasma for androgenetic alopecia: A review of the literature and proposed treatment protocol. Int J Womens Dermatol. 2018;5(1):46-51.

10. Pillai JK, Mysore V. Role of Low-Level Light Therapy (LLLT) in Androgenetic Alopecia. J Cutan Aesthet Surg. 2021;14(4):385-391.

11. Eginli A, Dothard E, Bagayoko CW, Huang K, Daniel A, McMichael AJ. A Retrospective Review of Treatment Results for Patients With Central Centrifugal Cicatrical Alopecia. J Drugs Dermatol. 2017;16(4):317-320.

12. Dillon KL. A Comprehensive Literature Review of JAK Inhibitors in Treatment of Alopecia Areata. Clin Cosmet Investig Dermatol. 2021;14:691-714. Published 2021 Jun 25. doi:10.2147/CCID.S309215

13. Gupta M, Mysore V. Classifications of Patterned Hair Loss: A Review. J Cutan Aesthet Surg. 2016;9(1):3-12.

14. Hausauer AK, Jones DH. Evaluating the Efficacy of Different PlateletRich Plasma Regimens for Management of Androgenetic Alopecia: A Single-Center, Blinded, Randomized Clinical Trial. Dermatol Surg. 2018;44(9):1191-1200.

15. Olsen EA, Weiner MS, Amara IA, DeLong ER. Five-year follow-up of men with androgenetic alopecia treated with topical minoxidil. J Am Acad Dermatol. 1990;22(4):643-646.

16. Schweiger ES, Boychenko O, Bernstein RM. Update on the pathogenesis, genetics and medical treatment of patterned hair loss. J Drugs Dermatol. 2010;9(11):1412-1419.

17. Borowiecka JM, Dalewski B, Pałka Ł. Effectiveness of Platelet-Rich Plasma in the Treatment of Androgenic Alopecia Compared to Placebo and Topical Minoxidil: A Systematic Review. Scientia Pharmaceutica. 2023;91(1):4.

18. Guo EL, Katta R. Diet and hair loss: effects of nutrient deficiency and supplement use. Dermatol Pract Concept. 2017;7(1):1-10. Published 2017 Jan 31. doi:10.5826/dpc.0701a01

19. Etminan M, Sodhi M, Procyshyn RM, Guo M, Carleton BC. Risk of hair loss with different antidepressants: a comparative retrospective cohort study. Int Clin Psychopharmacol. 2018;33(1):44-48. doi:10.1097/YIC.0000000000000191

20. Lopez-Leon S, Wegman-Ostrosky T, Perelman C, et al. More than 50 long-term effects of COVID-19: a systematic review and meta-analysis. Sci Rep. 2021;11(1):16144. Published 2021 Aug 9. doi:10.1038/s41598-021-95565-8